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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,437	12/17/2001	Stephen A. Johnston	UTSD:736US/MBW	2358

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,437	JOHNSTON ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-27,29-45,50-61 and 74-91* is/are pending in the application.

4a) Of the above claim(s) *26-38,50-61 and 76-81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25, 39-45, 74-75 and 82-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O

FINAL ACTION

1. This Office Action is responsive to Applicant's amendment and response filed March 14, 2005. Claims 25, 39-42, 44, 74-75 and 82-83 have been amended. Claims 85-91 have been added. Claims 1-24, 28, 46-49 and 62-73 have been cancelled. Claims 26-38, 50-61 and 76-81 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Applicant's submission of the declaration (by Dr. Akira Takashima) filed under 37 C.F.R. ~~1.131~~ 1.132 is acknowledged. Type-O sorry

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Objection Withdrawn

3. In view of Applicant's amendment the objection to claims 40-41, page 4, paragraph 2 is withdrawn.

Rejections Maintained

4. The rejection under 35 U.S.C. 112, first paragraph is maintained for claims 25, 39-45, 74-75, 82-83 and newly submitted claims 84-91 for the reasons set forth on pages 3-5, paragraph 3 of the previous Office Action.

The rejection was on the grounds that the claims while being enabling for a method of immunizing an animal comprising providing to the animal; at least one *Chlamydia* antigen corresponding to SEQ ID No. 9 or SEQ ID No. 7 and further comprising a second *Chlamydia* antigen corresponding to SEQ ID No. 11 or SEQ ID No. 13 does not reasonably provide enablement for all antigenic fragments of the SEQ ID Nos. 7, 9, 11 or 13 encompassed by the claims that can be used in the claimed method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teaches that the term "fragment " is defined as a sequence having at least 5 or more contiguous residues but less than the full-length of the SEQ ID Nos. (page 13). The specification teaches that it is contemplated that the definition of "fragment" can be applied to amino acid as well as nucleic acid fragments (page 13). The specification refers to the "antigenic fragment" as a fragment that can elicit an immune response in an animal (page 13).

The specification has failed to provide a structure for all of the antigenic fragments encompassed by the claimed invention.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of the protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and still retain similar activity requires a knowledge with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification) and detailed knowledge of the ways in which the protein's structure relates to function. However, the problem of the prediction of protein's structure from mere sequence data of a single protein and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect thereto is extremely complex and outside of the realm of routine experimentation.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple substitutions or multiple modifications of other types and the positions within the protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polynucleotide and the result of such modifications is unpredictable based on the instant disclosure. One skilled in the art would expect any tolerance to modifications. The sequence of some proteins is highly conserved and one skilled in the art would not expect tolerance to any amino acid modification in such protein.

Thomas E. Creighton, in his book, *"Proteins: Structures and Molecular Properties, 1984"*, (page 315) teaches that variation of the primary structure of a protein can result in an instable molecule. He teaches that a single amino acid change can cause a mutant hemoglobin to have lower stabilities due to any of several causes: 1) alteration of close-packing of the interior; loss of one group that normally participates in a hydrogen bond or salt bridge; 2) the introduction of a charged or polar group into the

alteration of close-packing of the interior; loss of one group that normally participates in a hydrogen bond or salt bridge; 2) the introduction of a charged or polar group into the interior or the insertion into a helical region of a proline residue, which must distort the alpha-helix; 3) while sometimes radical changes of surface groups, even introduction of a non-polar side chain- have no great effect on stability.

Thomas E. Creighton, in his book *"Protein Structure: A Practical Approach, 1989; pages 184-186"* teaches that present day site directed mutagenesis of a gene allows any amino acids in a protein sequence to be changed to any other, as well as introducing deletions and insertions". The reference goes on to teach that it is difficult to know which amino acid to change and which is the best residue to substitute for the desired functional and structural effect.

Nosoh, Y. et al in *"Protein Stability and Stabilization through Protein Engineering, 1991"* (chapter 7, page 197, second paragraph) adds support to Thomas E. Creighton, by teaching that results so far accumulated on the stability and stabilization of proteins appear to indicate that the strategy for stabilizing proteins differ from protein to protein and that any generalized mechanisms for protein stability have not yet been presented.

There is no guidance provided in the specification as how one would begin to choose all "antigenic fragments" of SEQ ID NOs. 7, 9, 11 or 13 encompassed by the claims. The specification does not support the broad scope of the claims, which encompass all modifications and fragments because the specification does <u>not</u> disclose the following:

- the general tolerance to modification and extent of such tolerance;
- specific positions and regions of sequence(s) which can be predictably modified and which regions are critical;
- what fragments, if any, can be made which the retain the biological activity if the intact protein; and
- the specification provide essentially no guidance as to which of the essentially infinite possible choice is likely to be successful.

Factors to be considered in determining whether undue experimentation is required are set forth in <u>In re Wands</u> 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting other proteins having claimed functional features, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or use proteins all antigenic fragments of SEQ ID Nos. SEQ ID Nos. 7, 9, 11 or 13 in manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

fragments of any size. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970). Without such guidance, the changes which can be made in the amino acid's structure and still maintain activity is unpredictable and the experimentation left those skilled in the art is unnecessarily and improperly, extensive and undue. See Amgen Inc v Chugai Pharmaceutical Co Ltd. 927 F 2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) at 18 USPQ2d 1026-1027 and Exparte Forman, 230 U.S. P.Q. 546(Bd. Pat=. App & int. 1986).

Applicant urges that the phrase "antigenic fragment refers to a fragment that can elicits an immune response in an animal. Applicant urges that the instant specification demonstrates that SEQ ID NOs. 7, 9, 11 and 13 can be used to immunize an animal. Applicant urges that a person of ordinary skill in the art would be able to make and use antigens and antigenic fragments as well as other antigenic fragments of SEQ ID NOs: 7, 9, 11 and 13 by following the teachings of the instant specification. Applicant urges that guidance for a person of ordinary skill in the art to make antigenic fragments of SEQ ID NOs. 7, 9, 11 and 13 can be found in the instant specification. Applicant refers to the declaration of Dr. Akira Takashima to support their position. The declaration submitted by Dr. Akira Takashima discloses that a scientist will understand that there would likely be other antigenic fragments of SEQs:7, 9, 11 and 13 that would elicit an immune response in an animal, because it is known to scientists in the fields of molecular biology and immunology that immunogenic proteins typically contain multiple immunogenic epitopes or determinants. Applicant urges that amended claims 40, 42 and 74 and newly submitted claims 84-91 have been submitted to place a lower limit on the length of the antigenic fragment.

Applicant's arguments filed March 14, 2005 have been fully considered but they are not persuasive. The claims are not limited to polypeptides that are fragments of SEQ ID NOs:7, 9, 11 and 13. The phrase "antigenic fragment" as defined by Applicant does not disclose, which amino acids are, deleted or substituted along the amino acid sequence to arrive at a fragment encompassed by the claimed invention? It should be remembered that the statute under 35 U.S.C. 112, first paragraph requires that the specification teach how to make and use polypeptides of the claimed invention not how to "find" fragments of the *Chlamydia* polypeptides (e.g. SEQ ID NOs. 7, 9, 11 and 13) used in the claimed method. A structure is required for the polypeptides used in the claimed method. It should be remembered while recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polypeptide and the result of such modifications is unpredictable based on the instant disclosure. One of skill in the art would require guidance to make and use the claimed isolated polypeptides. To address the declaration submitted by Dr. Akira Takashima, it must be noted that the claimed invention encompasses any number of fragments of SEQ ID NOs. 7, 9, 11 and 13. Therefore, a structure for these fragments is required.

To address Applicant's comments regarding amended and newly submitted claims that place a lower limit on the fragments encompassed by the claims, even though a low limit is now recited in the claims, Applicant has not provided a structure for the plurality

of polypeptides encompassed by the claims. Therefore, Applicant has not met the burden required under 35 U.S.C. 112, first paragraph.

5. The rejection under 35 U.S.C. 112, second paragraph is maintained for claims 25, 39-45, 74-75, 82-83 and newly submitted claim 84 for the reasons set forth on page 9, paragraph 4 of the previous Office Action.

The rejection was on the grounds that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 recites "providing to the animal". It is not clear as to what Applicant is referring. Does Applicant mean that the *Chlamydia* antigen is administered to the animal? The language of the claims is not as precise as the subject matter permits such that one would reasonably know the metes and bounds of the claimed subject matter. Correction is required.

Applicant urges that some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the Examiner might desire. Applicant urges that the phrase "providing to an animal" is reasonably clear to one of ordinary skill in the art.

Applicant's arguments filed March 14, 2005 have been fully considered but they are not persuasive. Even though some latitude must be give to the claim language, the metes and bound of the claim language must be ascertained. The claims are directed to a method of immunizing. What is the active step in the claimed method? What does the phrase "providing to an animal" mean? Does providing to the animal mean that the composition is administered to the animal? Clarification is required.

6. The rejection under 35 U.S.C. 102(e), is maintained for claims 25, 39, 41, 43, 45 and 82-83 for the reasons set forth on pages 10-11, paragraph 5 of the previous Office Action.

The rejection was on the grounds that Griffais et al teach a method of immunizing an animal comprising administering vaccine compositions comprising at least one *Chlamydia* antigen or antigenic fragment in an amount to induce an immune response (columns 62-64). Graffais et al teach that the vaccine composition are administered to a mammalian host (column 62) including humans (column 63). Griffais et al teach that any number of antigens may be included in the invention (see Table 1). Griffais et al teach that antigen from *Chlamydia psittaci* may be included in the invention. Therefore, the prior art meets the claim limitation "...wherein the method is effective to induce an immune response against *Chlamydia psittaci*". The prior art teaches antigenic fragments of SEQ ID Nos. 7 and 9 (corresponding to the first *Chlamydia* antigen) as well as antigenic fragments of SEQ ID Nos. 13 (corresponding to the second *Chlamydia* antigen). SEQ ID NO: 59 of the prior art corresponds to fragments of SEQ ID NOs: 7 and 9. SEQ ID NO: 12 of the prior art corresponds to antigenic fragments of SEQ ID NO:13. See the attached sequence alignments.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that to anticipate a claim the prior art must teach each and every element of the claimed invention. Applicant urges that the Office action fails to identify where the method of immunizing is taught in the prior art. Applicant urges that the prior art must be enabling and describe Applicant's invention. Applicant states "that a person of ordinary skill in the art would not have been placed in possession of a method of immunizing an animal by providing to the animal at least one *Chlamydia psittaci* antigen or antigenic fragment thereof in an effective amount to induce an immune response. Applicant urges that since claims 40, 42 and 74 place a lower limit on the length of the

sequences used in the claimed method then the sequences are novel over the cited prior art. Applicant urges that the action fails to establish a *prima facie* case of anticipation.

Applicant's arguments filed March 14, 2005 have been fully considered but they are not persuasive. Applicant asserts that Graffais et al do not teach a method of immunizing an animal. It should be noted that the prior art teaches that the immunogenic compositions and vaccine of the invention comprising *Chlamydia* antigens were administered to mice (column 63). Graffais et al teach that a weight dose of the vaccine composition as comparable to the dose used in humans is administered to the animals and the antibody reaction is tested (column 63). Graffais et al teach that the efficacy of the vaccine compositions can be determined by challenging animal models of *Chlamydia pneumoniae* infection after administration of the vaccine of the invention (column 63). Graffais et al teach that mice were immunized with the vaccine compositions of the invention (column 64). Therefore, the prior art teaches that claimed method. To address Applicant's comment regarding claims 40, 42 and 74, these claims have been removed from this rejection. To address Applicant's comment's regarding possession and enablement of the claimed invention, it should be remembered that issues regarding possession and enablement are addressed under 35 U.S.C. 112, first paragraph and not under 35 U.S.C.102. Applicant has provided no side-by-side comparison to show that the claimed method differs from that of the prior art. Graffais et al anticipate the claimed invention.

7. The rejection under 35 U.S.C. 102(b), is maintained for claims 25, 39, 41,43, 45, and 82-83 for the reasons set forth on pages 11-12, paragraph 6 of the previous Office Action.

The rejection was on the grounds that Griffais et al teach a method of immunizing an animal comprising administering vaccine compositions comprising at least one *Chlamydia* antigen or antigenic fragment in an amount to induce an immune response (page 71-73). Graffais et al teach that the vaccine composition are administered to a mammalian host including humans (pages 72-73). Griffais et al teach that any number of antigens may be included in the invention (see Table 1). Griffais et al teach that antigen from *Chlamydia psittaci* may be included in the invention. Therefore, the prior art meets the claim limitation "...wherein the method is effective to induce an immune response against *Chlamydia psittaci*". The prior art teaches antigenic fragments of SEQ ID Nos. 7 and 9 (corresponding to the first *Chlamydia* antigen) as well as antigenic fragments of SEQ ID Nos. 13 (corresponding to the second *Chlamydia* antigen). SEQ ID NO: 59 of the prior art correspond to fragments of SEQ ID NOs: 7 and 9. SEQ ID NO: 12 of the prior art correspond to fragments of SEQ ID NO:13. See the attached sequence alignments.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that to anticipate a claim the prior art must teach each and every element of the claimed invention. Applicant urges that the Office action fails to identify where the method of immunizing is taught in the prior art. Applicant urges that the prior art must be enabling and describe Applicant's invention. Applicant states "that a person of ordinary skill in the art would not have been placed in possession of a method of immunizing an animal by providing to the animal at least one *Chlamydia psittaci* antigen or antigenic fragment thereof in an effective amount to induce an immune response. Applicant urges that since claims 40, 42 and 74 place a lower limit on the length of the

sequences used in the claimed method then the sequences are novel over the cited prior art. Applicant urges that the action fails to establish a *prima facie* case of anticipation.

Applicant's arguments filed March 14, 2005 have been fully considered but they are not persuasive. Applicant asserts that Graffais et al do not teach a method of immunizing an animal, It should be noted that the prior art teaches that the immunogenic compositions and vaccine of the invention comprising *Chlamydia* antigens were administered to mice (page 72). Graffais et al teach that a weight dose of the vaccine composition as comparable to the dose used in humans is administered to the animals and the antibody reaction is tested (page 71). Graffais et al teach that the efficacy of the vaccine compositions can be determined by challenging animal models of *Chlamydia pneumoniae* infection after administration of the vaccine of the invention (page 71). Graffais et al teach that mice were immunized with the vaccine compositions of the invention (page 71). Therefore, the prior art teaches that claimed method. To address Applicant's comment regarding claims 40, 42 and 74, these claims have been removed from this rejection. To address Applicant's comment's regarding possession and enablement of the claimed invention, it should be remembered that issues regarding possession and enablement are addressed under 35 U.S.C. 112, first paragraph and not under 35 U.S.C.102. Applicant has provided no side-by-side comparison to show that the claimed method differs from that of the prior art. Graffais et al anticipate the claimed invention.

New Grounds of Rejection Necessitated by Amendment

Claim Objection

8. Claim 86 is objected for the following informality: the term "lease" should be changed to "least". Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Newly amended claims 40, 42, 74-75 and newly submitted claims 85-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.* The amendment filed March 14, 2005 introduced new matter into the claims.

Amended claims 40, 42, 74-75 and newly submitted claims 84-91 introduce new matter in the claims because "the phrases wherein the antigenic fragment comprises at least 15 contiguous amino acid resides of SEQ ID NO:7", ...or an antigenic fragment thereof comprising at least 15 contiguous amino acid residues of SEQ ID NO NO:13", "...or an antigenic fragment thereof comprising at least 25 contiguous amino acid residues of SEQ ID No.9" and "...or an antigenic fragment thereof comprising at least

15 contiguous amino acid residues of SEQ ID NO:11 are not disclosed, taught or supported in the instant specification. Applicant has failed to direct the Examiner to where in the instant specification the support for this amendment is specifically shown or implied. The Examiner has reviewed the instant specification and has failed to find the support for the amendment. Removal of the phrases from the claims is requested.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 39-45, 74-75 and 82-84 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 39-45, 74-75 and 82-84 do not further limit claim 25. In fact, claims 39-45, 74-75 and 82-84 broaden the scope of claim 25. Claims 39-45, 74-75 and 82-84 broad the scope of claim 25 because they recite "... at least one *Chlamydia psittaci* antigen and fragments thereof" and claim 25 only recites "...at least one *Chlamydia psittaci* antigen. Correction is required.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Status of Claims

12. No claims allowed.

Conclusion

13 Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VLF

Vanessa L. Ford
Biotechnology Patent Examiner
May 24, 2005

LRFS

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